



DOCKET NO.: JACB-0053

PATENT

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

**In Re Application of:**

**David P. Jacobus, et al.**

**Confirmation No.: 6080**

**Application No.: 10/716,283**

**Group Art Unit: 1614**

**Filing Date: November 18, 2003**

**Examiner: Not Yet Assigned**

**For: BIGUANIDE AND DIHYDROTRIAZINE DERIVATIVES**

DATE OF DEPOSIT: *March 2, 2004*

I HEREBY CERTIFY THAT THIS PAPER IS BEING DEPOSITED WITH THE UNITED STATES POSTAL SERVICE AS FIRST CLASS MAIL, POSTAGE PREPAID, ON THE DATE INDICATED ABOVE AND IS ADDRESSED TO THE UNITED STATES PATENT AND TRADEMARK OFFICE, P.O. BOX 1450, ALEXANDRIA, VA 22313-1450.

*Elizabeth A. McLoud*

TYPED NAME: Elizabeth A. McLoud

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Dear Sir:

**INFORMATION DISCLOSURE STATEMENT**

Pursuant to 37 CFR § 1.56 and in accordance with 37 CFR §§ 1.97-1.98, information relating to the above-identified application is hereby disclosed. Inclusion of information in this statement is not to be construed as an admission that this information is material as that term is defined in 37 CFR § 1.56(b).

In accordance with § 1.97(b), since this Information Disclosure Statement is being filed either within three months of the filing date of the above-identified application, within three months of the date of entry into the national stage of the above identified application as set forth in § 1.491, before the mailing date

of a first Office Action on the merits of the above-identified application, or before the mailing date of a first Office Action after the filing of request for continued examination under § 1.114, no additional fee is required.

- In accordance with § 1.129(a), this Information Disclosure Statement is being filed in connection with  the first or  second After Final Submission, therefore:
  - Certification in Accordance with § 1.97(e) is attached; or
  - The fee of \$180.00 as set forth in § 1.17(p) is attached.
- In accordance with § 1.97(c), this Information Disclosure Statement is being filed after the period set forth in § 1.97(b) above but before the mailing date of either a Final Action under § 1.113 or a Notice of Allowance under § 1.311, or before an action that otherwise closes prosecution in the application, therefore:
  - Certification in Accordance with § 1.97(e) is attached;
  - or
  - The fee of \$180.00 as set forth in § 1.17(p) is attached.
- In accordance with § 1.97(d), this Information Disclosure Statement is being filed after the mailing date of either a Final Action under § 1.113 or a Notice of Allowance under § 1.311 but before, or simultaneously with, the payment of the Issue Fee, therefore included are: Certification in Accordance with § 1.97(e); and the submission fee of \$180.00 as set forth in § 1.17(p).
- Copies of each of the references listed on the attached Form PTO-1449 are enclosed herewith.

- Copies of references listed on the attached Form PTO-1449 are enclosed herewith
- Copies of references listed on the attached Form PTO 1449 are not required to be submitted pursuant to the June 30, 2003 recent revisions to 37 CFR § 1.98(a)(2)(i).

EXCEPT THAT:

- In view of the voluminous nature of references [list as appropriate], and the likelihood that these references are available to the Examiner, copies are not enclosed herewith.
- In accordance with § 1.98(d), copies of the following references listed on the attached Form PTO-1449 are not enclosed herewith because they were previously cited by or submitted to the U.S. Patent and Trademark Office in patent application(s) for which a claim for priority under 35 U.S.C. § 120 have been made in the instant application:
  - Copies of references [list as appropriate] listed on the attached Form PTO-1449 were previously cited by or submitted to the Patent and Trademark Office in prior Application No. , filed .

Please charge any deficiency or credit any overpayment to Deposit Account No. 23-3050. This form is submitted in duplicate.

The relevance of those listed references which are not in the English language is as follows:

There are no listed references which are not in the English language.

Date: *March 1, 2004*

  
\_\_\_\_\_  
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<b>Form PTO-1449 Modified</b>  List of Patent and Publications Cited by Applicant (Use several sheets if necessary)  U.S. Department of Commerce Patent and Trademark Office	Docket No. JACB-0053	Application No. 10/716,283
	Applicant David P. Jacobus, et al.	
	Filing Date November 18, 2003	Group 1614
	Confirmation No. 6080	

**OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)**

	1	Bergeron, R.J., et al., "Mild oxidation of alkyl halides," <i>J. Org. Chem.</i> , <b>1979</b> , <i>44</i> (11), 1835-1839
	2	Carey, F.A., et al., Advanced Organic Chemistry, Part B: Reactions and Synthesis, 3 <sup>rd</sup> Ed., <i>Plenum Press, New York</i> , <b>1990</b> , 588-591
	3	Crowther, A.F., "Synthetic antimalarials. Part XXIX. The preparation of some N <sup>1</sup> -aryl-N <sup>2</sup> -alkyl-N <sup>5</sup> -alkyl- and -dialkyl-diguanides," <i>J. Chem. Soc.</i> , <b>1948</b> , 1636-1645
	4	Curd, F.H.S., et al., "Synthetic antimalarials. Part XXVIII. An alternative route to N <sup>1</sup> -aryl-N <sup>5</sup> -alkyldiguanides," <i>J. Chem. Soc.</i> , <b>1948</b> , 1630-1635
	5	Davidson, J.S., "A preparation of N-alkyl-N'-cyano-S-methylisothioureas," <i>Chemistry and Industry</i> , November 27, <b>1965</b> , 1977-1978
*	6	Gennaro, A.R. (Ed.), Remington's Pharmaceutical Sciences, 17 <sup>th</sup> Ed., <i>Mack Publishing Co., Easton, PA</i> , <b>1985</b>
	7	Greene, T.W., et al., Protective Groups in Organic Synthesis, 2 <sup>nd</sup> Ed., <i>John Wiley &amp; Sons, Inc.</i> , <b>1991</b> , 117-118
	8	Jensen, N.P., et al., "Phenoxypropoxybiguanides, prodrugs of DHFR-inhibiting diaminotriazine antimalarials," <i>J. Med. Chem.</i> , <b>2001</b> , <i>44</i> , 3925-3931
	9	Knight, D.J., et al., "The antimalarial activity of N-benzyl oxydihydrotriazines," <i>Annals of Tropical Med. &amp; Parasitol.</i> , <b>1980</b> , <i>74</i> (4), 393-404
	10	Knight, D.J., et al., "The antimalarial activity of N-benzyl-oxydihydrotriazines," <i>Annals of Trop. Med. &amp; Parasitol.</i> , <b>1982</b> , <i>76</i> (1), 9-14

EXAMINER	DATE CONSIDERED
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\* A copy of this reference will not be forwarded to the U.S. Patent and Trademark Office since it is believed to be too voluminous and easily obtainable by the Examiner.

<b>Form PTO-1449 Modified</b>		Docket No. JACB-0053	Application No. 10/716,283
List of Patent and Publications Cited by Applicant (Use several sheets if necessary)		Applicant David P. Jacobus, et al.	
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		Confirmation No. 6080	
<b>OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)</b>			
	<b>11</b>	Larock, R.C., Comprehensive Organic Transformation, : <i>VCH Publishers, New York, 1989</i> , 353-363	
	<b>12</b>	Onori, E., et al., "Recent acquisitions on chemotherapy and chemoprophylaxis of malaria," <i>Ann. 1<sup>st</sup> Super Sanita.</i> , <b>1989</b> , 25(4), 659-673	
<b>EXAMINER</b>		<b>DATE CONSIDERED</b>	

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**U. S. PATENT DOCUMENTS**

Examiner Initial		Document No.	Date	Name	Class	Subclass
	13	3,723,429	03/27/73	Mamalis, et al.	260	249.9
	14	4,179,562	12/18/79	Ponsford	544	298
	15	4,232,022	11/04/80	Ponsford	424	251
	16	5,322,858	06/21/94	Canfield, et al.	514	635
	17	5,538,812	07/23/96	Lee, et al.	429	192

**FOREIGN PATENT DOCUMENTS**

Examiner Initial		Document No.	Date	Country	Translation	
					YES	NO

<b>EXAMINER</b>	<b>DATE CONSIDERED</b>
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